REMARKS

1. Definiteness Issues

1.1. We have corrected the language of claim 1 a suggested by the examiner. Claim 1 now also explicitly states that the application zone and detection zone are separate.

1.2. In claim 42, we have deleted "said kit comprising". We have also added a "wherein" clause to step (c) to connect it better to step (d).

1.3. Claim 56 is intended to depend from 55.

1.4. Claims 59-76 have been added.

2. Prior Art Issues

Claims 1-3, 8-20, 24, 25, 28, 30-36, 42, 45, 46 and 48-58 stand rejected as obvious over Swiekosz et al. in view of Tsutsumi et al., Ouchi et al., and Lihme et al. Claims 21-23, 26, 27, 37-41, 43 and 47 stand rejected as obvious over the aforementioned art, together with Sheeran et al. These rejections are respectfully traversed.

Our kit claim 1 recites that the application zone comprises the conjugate, that the conjugate is movable, that the application zone is in liquid contact with the detection zone, and that the conjugate is detected in the detection zone. (As amended, it makes it clear that the two zones are separate.)

Method claim 24 recites use of the kit of claim 1 and the detection, in the detection zone, of said conjugate, "wherein the detection of the conjugate is indicative of the presence of RS virus infected cell or RS virus biological particle in the sample". The latter implies that, initially, there is no conjugate in the detection zone; this is made explicit in new claims 59 and 60.

The art does not disclose or suggest use of the recited multifunctional conjugate in an assay in which the conjugate is moved by the sample from an application zone to a detection zone.

Lihme et al. (US 5,543,332) disclose water soluble reagents comprising a water soluble polymeric carrier molecule having attached thereto more than one connecting moiety wherein the connecting moiety is attached to a reactive functional group on the polymeric carrier molecule. The connecting moiety may act as coupler to a labeling species, a marking species and targeting species. The reference describes the use of the water soluble reagents in ELISA procedures and in Dot Blot immunoblotting.

There is no disclosure of the use of the water soluble reagents in a dipstick, or a like device, in particular, no disclosure of the possibility of having the water soluble reagents flowing from an application zone to a detection zone in an assay kit.

Lihme presents a list of procedures or techniques of different types at col. 18 line 49-63 wherein the conjugate of Lihme is thought to be useable. None of these procedures or techniques is directly detecting a particle based on any kind of solid support with an application zone and detection zone separate from each other and where the conjugate moves from the application zone to the detection zone. Rather, in the procedures or techniques mentioned by Lihme, the species to be detected is moved to a 'detection zone' if moved at all, before the conjugate is added to the assay container.

Furthermore, there is no hint in Lihme et al. that the water soluble reagents may be used in a dipstick or the like where the conjugate has to move along or within a solid support, since the only applications in Lihme et al. are ELISA and Dot Blot as mentioned in col. 21 line 14-16 and col. 22 line 32-34.

When Lihme state that the polymeric conjugate is water soluble this does not ensure that it is moved, or even movable, within a solid support. Thus, the fact that the conjugate in the present invention is movable, and indeed is deliberately moved, is indeed an unpredictable feature.

Tsutsumi describes a paper membrane (p. 2007, 2nd col, para. 4), where the specimen migrates via capillary action along the membrane (p. 2007, 2nd col., para. 4), adenovirus-signal antibody complex reacts with the polyclonal antibody to adenovirus and forms a colored line (p. 2008, 1st col, para. 1). The excess signal antibody migrates further until it reacts with the polyclonal antibody to mouse immunoglobulin, producing a separate, second colored line (p. 2008, 1st col, para. 1). Thus, two colored lines on the test stick indicate the presence of adenovirus hexon antigen (p. 2008, 1st col, para. 1).

In the method described by Swiekosz et al a reagent or washing solution was added seven times before the result could be observed (figure 1 and p 1152, 1st col., para. 4). There is no description of migration by capillary action or other forces along a membrane, rather figure 1 shows that all the reactions on the solid support are obtained within the same area. This method is very different from the method of Tsutsumi as described above, thus it is not obvious for the skilled person to combine these documents. This combination is a pure hindsight combination.

It is pure hindsight to state that it was obvious to substitute the signal antibody of Tsutsumi with the water soluble reagents of Lihme et al, as the water soluble reagents of Lihme are not described to be movable.

In particular, Swiekosz et al, Tsutsumi et al, Ouchi et al and Lihme do not collectively teach a person of ordinary skill in the art to make the invention as claimed by the present claim 1, wherein different zones, in liquid contact with each other, may be used for applying the sample and detecting bound conjugates, respectively, by utilising a moveable conjugate.

Accordingly, the invention as claimed by claim 1 is non-obvious in view of Swiekosz et al further in view of Tsutsumi et al, Ouchi et al and Lihme et al. Thus claim 1-3, 8-20, 24, 25,

28, 30-36, 42, 45, 46 and 48-58 are not obvious in view of these documents.

Sheeran et al does not add anything regarding the method and especially not regarding a movable conjugate. Thus, in view of the above mentioned arguments the claims 21-23, 26, 27, 37-41, 43 and 47 are also nonobvious.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: _____
Iver P. Cooper
Reg. No. 28,005

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms
G:\ipc\g-i\hoib\Lassen2A\PTO AMEND2.WPD